EXHIBIT C

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO PLAINTIFFS: Christine Wiltgen Case No. 2:12-cv-01216 Laura Waynick Case No. 2:12-cv-01151 Denise Burkhart Case No. 2:12-cv-01023 Debra A. and Donald Schnering Case No. 2:12-cv-01071 Karen Bollinger Case No. 2:12-cv-01215	

GENERAL DEPOSITION OF
KIMBERLY KENTON, M.D.
March 25, 2016
Chicago, Illinois

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A. Yes. Sorry. Yes, if I recall.

Q. We don't have you on video today. I just have to wait until you give an affirmative answer.

A. Yeah, I apologize.

Q. Now, you use the retropubic device in the majority of your patients instead of the transobturator procedure, correct?

A. I do.

Q. And why is that?

A. Several reasons, the first being I think that when you look -- although the long-term outcome data, you can't declare them equivalent or not equivalent in our own study, there was a slightly higher cure of stress incontinence with the retropubic.

And I think that that's consistent with what we understand, what we think we understand about incontinence procedures is the more obstructive they are, the more likely they are to cure stress incontinence and possibly induce a little bit more urgency. So...

Q. Is there any other reason that you use the retropubic over the transobturator?

A. That's probably the primary one. I do occasionally use transobturators. I tend to reserve that for women who have had prior extensive retropubic surgery where I am concerned that there may be bowel in the retropubic space or sometimes older women who I think I would rather have them less likely to be cured and less -- induce less urgency and voiding dysfunction.

Q. And you agree with me that the TVT-O in the reported literature has a higher rate of groin pain in women than the TVT-R, correct?

MR. ROSENBLATT: Object to form.

BY THE WITNESS:

A. In the reported literature, particularly in the short term, TVT has higher rates of groin pain. In contrast, the TVT has slightly higher rates of suprapubic pain. So, yes, I think there is a difference in the two procedures.

BY MS. FITZPATRICK:

Q. And you agree with me that the TVT-O and the TVT-R have different risks and benefits associated with the particular procedures, correct?

A. Agreed.

Q. Okay. And would you agree with me that

the TVT-O has a higher rate of leg pain in the reported literature than the TVT-R?

A. Yes, I would agree with that.

Q. And would you agree with me that the TVT-O has a higher rate of vaginal perforation reported in the literature than the TVT-R?

A. I would agree with that.

Q. Now, when we talked a few months ago you told me that you rarely do a transobturator sling and that it's only in carefully selected women. Does that sound accurate?

A. It does.

Q. And I think what you told me is you use it in older women. But can you tell me now what are the characteristics of the carefully selected women on whom you choose to do an obturator procedure rather than the retropubic procedure?

A. So, as I said, people who have had extensive prior retropubic surgery where their retropubic space may have been opened like from having a prior Burch and a hysterectomy at the same time. Sometimes there can be bowel in that space. So, I prefer not to be in the retropubic space.

And then the other big group of women

want to know if you're aware of anything. I think what you're telling me is you don't know of any studies that have been done like that and you don't know how such a study would even be conducted. Is that fair enough?

MR. ROSENBLATT: Object to form.

BY THE WITNESS:

A. I wouldn't know how to conduct that study.

BY MS. FITZPATRICK:

Q. Okay. Do you know of any clinical trials that have been done to assess specifically the safety of the TVT-O device made by Ethicon?

A. So, a clinical trial by definition is comparative. You can't really do a randomized controlled trial to look at safety because, fortunately, most of these complications are rare. So, most of the clinical trials are designed to look at efficacy with safety endpoints.

And then it brings us to the systematic reviews and the meta-analyses where we use, fortunately, validated outcome measures that we can try to compile those to more objectively look at safety.

rare?

A. Sure. I mean, I'm not sure I walk around with a clear cutoff of what rare is.

Q. Okay. But somewhere in that neighborhood?

A. Yeah.

Q. Okay. You know, though, that there are complications that are unique to the helical trocars that are used with the TVT-O versus the trocars that are used with the TVT Retropubic, correct?

A. So, can we just like upfront -- I think that there are unique complications associated with the transobturator route of sling placement that differ from the retropubic. I don't know if it's from the trocar or the sling or if I just took a surgical instrument and put it through that space it would be different. Do you understand the difference in those?

Q. Okay.

A. Let's just like so we don't have to keep going back to that thing. I think that there are differences in complications with the two procedures, whether it's the trocar, whether it's

the method of passage.

I mean, I could theoretically say that I could just take a surgical instrument and still pass it like how we used to with old-fashioned retropubic slings. That's exactly how we pass the TVT. It's not that different.

If I took a uterine packing forceps and pass it through the transobturator space, I think we would see similar complications that are unique to passing something through the transobturator space.

Q. Okay. So, let's --

A. It's the route of access more than I think it's the device, like that particular trocar.

Q. So, with -- just let me see if I have got this right.

So, what you're saying with the TV -- some of the unique complications, and we can get to what those are, but those unique complications with the obturator procedure, you think are more related to the route of access through the obturator space than the actual trocar itself causing the injury?

A. Correct.

Q. Is that -- okay.

used in both the TVT-O and the TVT-R from a Class I device to a Class II device?

MR. ROSENBLATT: Take your time to read through the document if that's what she's asking you about.

THE WITNESS: I don't think she's asked me that.

BY MS. FITZPATRICK:

Q. No, I was asking you whether you knew --

A. Yeah.

Q. -- that the FDA had proposed that.

A. No.

Q. So, if you take a look at what's in front of you, and this came out in February 26 of 2016.

Have you seen or has anyone from Ethicon made you aware that the FDA is looking at reclassification of urogynecological surgical mesh instrumentation?

A. No.

Q. If you take a look at this document, on -- in the "Conclusion" section, on page 22, it reads, "The FDA proposes that urogynecologic surgical mesh instrumentation are reclassified from

Class I to Class II with special controls and be subject to pre-market notification requirements."

Do you see that?

A. I do. It's great.

Q. And this came out -- why do you say that's great?

A. Because should have had this type of an approval process for all surgical devices 20 years ago.

Q. So, you think this would have been a good thing to have the trocars classified as a Class II device instead of a Class I device from the time that they have been on the market?

A. I don't -- as I said, I'm not -- I'm not so sure I agree with them that it's about the instrumentation as much as the whole -- this is similar to the whole procedure.

I think that for, as you know, for a surgical procedure to get approved ten years ago, five years ago, it didn't have to be even implanted in people based on the 510(k) approval process.

So, I think all this is going to benefit women and men because it applies to many other fields of medicine as well.

surgical procedure safer in association with the TVT-R device. Do you recall that?

MR. ROSENBLATT: Object to form.

BY THE WITNESS:

A. So, I had conversation -- I told you that we had conversations, not with -- about -- with a different company. My fellows had. With a -- so, not TVT-R.

But a retropubic midurethral sling or transobturator regarding tensioning to more standardize tensioning. Didn't make it safer. It made it easier to standardize when you're teaching.

BY MS. FITZPATRICK:

Q. Okay. But you will agree with me that you also had the opinion that some of the complications are caused by overtensioning the device at the time of implant, correct?

A. I think that that's a million dollar question. If we could figure out exactly how to tension it the same way for every woman, but yes.

I think that all slings that you can put in like more tightly, they are going to be more obstructive and they will create more voiding dysfunction.

Q. Okay. So, I think that what we had discussed was that --

A. I would be retired and not sitting here if I knew how to tension it exactly right for every woman.

Q. Okay. And, so, that's something that is inherent in the transobturator midurethral slings as well, the difficulty in getting consistent tensioning from patient to patient to patient to patient, correct?

A. Yeah. I think that -- I think -- I think what I meant to say or what I implied or wanted to say was it's not inherent.

So, you don't -- you are trying to compensate for a nerve and a muscle that don't work. How sick your nerve and muscle are may be different, if you have incontinence, may be different than how sick mine is.

I think that one of the limitations of all continence procedures is how do I decide how to tight to make it for you that you can void freely and not have stress incontinence. It may be different for me.

And I think that that's uniform across

all continence procedures and that's to me the million dollar question that we can move beyond.

But then there is this way, since we don't really know who needs a tighter one or a looser one, that when you are doing multiple times, and I train residents and fellows, that I got to just standardize how we do it.

And one of the things that I found useful was what you were referring to is putting a Babcock or a surgical instrument to just sort of keep that standard.

I don't know that it makes it safer by doing that. Some people may leak more. But I think that that's -- we don't know the perfect way to tension any sling, whether it be -- or any continence procedure for that matter.

Q. And the reason that it's difficult is the pelvic anatomy of women can be marginally different, correct? My nerves may not be exactly where your nerves are?

A. I would say it's different because there is probably a multifactorial etiology for what causes stress incontinence in women, and we are not fixing the underlying.

So, we think women have stress incontinence and the propensity of the data is because you have a neuromuscular injury to the striated urethral sphincter, which is -- a simple analogy. Think of your bladder as a birthday party balloon. Little spigot. Knot on the end. The knot is the urethral sphincter.

So, the nerve that goes to innervate that muscle doesn't work as well. The muscle is not as strong. I can't make that nerve or that muscle better. So, all incontinence procedures inherently like work to compensate for that in some way.

Q. So, are you saying it doesn't cure the underlying cause of the stress urinary incontinence; it tries to manage the symptoms --

A. Yes.

Q. -- around the --

A. I would agree with that statement.

Q. Okay. And, so, when you are looking at implanting whether it's a retropubic or a transobturator sling to manage that complication, there is no way -- and you're implanting it in women -- the women's anatomy, just even where you

place that sling, is a little bit different from woman to woman to woman, correct?

Like a woman -- let me ask it like this. A woman who is 100 pounds isn't going to be -- have the same exact pelvic anatomy sitting placement-wise as a woman who is 200 pounds, is she?

MR. ROSENBLATT: Object to form.

BY THE WITNESS:

A. I think that a woman -- two women that are -- weigh 90 pounds aren't going to have the same anatomy as each other. The same way no one has the same nose or the same eyes. So, yes.

BY MS. FITZPATRICK:

Q. So, the pelvic anatomy differs from woman --

A. Be identical twins.

Q. -- to woman to woman.

Even then, it's probably not exactly the same, is it?

A. Yeah, you're right.

Q. So, when you're implanting into women, you have to take -- attempt, to the best of your ability, to take into account the differences in

the placement of a woman's anatomy, correct?

A. Yeah.

Q. And that's a difficult thing to do from patient to patient to patient to patient, correct?

A. I don't think it's a difficult thing to do.

Q. You think that all doctors are able to easily place a transobturator sling with the correct tensioning with the correct placement every time from woman to woman to woman even given that difference in anatomy?

MR. ROSENBLATT: Object to form.

BY THE WITNESS:

A. I don't know that the correct -- yeah, I don't think that the anatomy is probably the big difference. I don't know that they can always tension it perfectly even in two people. I'm not sure -- I'm not sure that the reason for the variation in outcomes is anatomic.

BY MS. FITZPATRICK:

Q. What is the reason for the variation in outcomes with tensioning?

A. I mean, I think that that would be -- I wish I knew that because then we could have 100

percent cure rates with stress incontinence. Nobody knows that.

People can give you theories, but like no one knows that because if they did, like, if you look at the rates of incontinence and pelvic floor disorders, they would just cure everybody and we could kind of move on.

Q. Okay.

A. I mean, that's the big question we have clinically is how do you find that one in ten -- like, you know, one in ten women who is still have some symptoms after you do an incontinence procedure on her.

Q. Let me move on to -- a little bit.

I think you've already told me that the risk profile with the TVT-O and the TVT-R are different, correct?

A. Correct.

Q. What is your opinion of the most frequent complications associated with the TVT-O procedure?

A. So, do you want to do this from just anecdotally from my recall or do you want to do it from the literature?

slings were an inherently bad procedure and it created disproportionate leg pain.

I don't believe taking the device off the market is going to make that go away because I could take an old surgical instrument the same way we did with fascial slings and put it through that space.

It's not the device. It's -- it's like -- if there is a problem, it's inherent. We had the same problems with fascial slings that we do with midurethral slings at much lower frequencies when we were -- do you understand the difference between that?

Like it's no different than using a forceps to put it through or they used to have -- like they made needles for needle suspensions.

Q. Okay. Let me ask you a couple --

MR. ROSENBLATT: Is someone on the phone?

MS. FITZPATRICK: There was. I think no longer, but there was an attorney from another law firm listening in.

BY MS. FITZPATRICK:

Q. Let me ask you something. I want to ask you two questions about your answer there.

Why do you think this lawsuit is about taking the TVT-O or the TVT-R off the market?

A. I don't. I didn't imply that it was.

But I think there is a lot of focus on the device, and I'm not sure it's -- I mean, if you think it's a bad technique, I'm not sure it's the device is the problem rather than the concept of putting something through the transobturator space.

Q. Do you think putting something through the transobturator space and leaving it there as a permanent implant, do you think that's a good idea?

A. Based on the data, for most women it works fine. They have high success rates and low complication rates.

Can I just -- do you understand like where I am trying to differentiate like the thing?

It's not -- let's say I did agree with that. Then -- so, like the Capio, like the -- that Boston Sci one. So, they are not using a device, but they're finding a way to suture to a ligament and -- you know what I mean?

Like it's not -- yeah. I don't think I can explain this. I don't know, but I think -- I don't -- to me when you talk about the device,

Q. And the TVT-O is designed by Ethicon to be implanted surgically through the obturator space, correct?

A. Correct.

Q. And sometimes that surgical placement can cause complications that are unique to the obturator midurethral slings, correct?

A. Correct. I can agree with all that.

Q. And in addition to the surgical procedure that you use through the obturator space, there is a piece of mesh that's used, correct?

A. Yes.

Q. And that mesh is left in the obturator space when you're done with your surgery, correct?

A. Correct.

Q. And that mesh in the whole pelvic region, that can cause certain complications for women, correct?

A. Correct.

Q. And, so, it seems to me that what this study is suggesting is that the complications that are related to the TVT-O either are related to the surgical route of implantation or the use of mesh.

And all I am asking is do you agree with

medium-term data at about five years. But, yes, we need to follow women for longer periods of time.

Q. Okay. And do you agree with this paper that larger studies with longer follow-up periods should identify risk factors for failure and then -- and thus lead to better preoperative consultation?

A. I don't think that -- I think it's a nice statement, but I don't think that you're going to get longer studies that are well done with longer term follow-up. I think it's going to have to be systematic reviews and meta-analyses that are trying to compile these things. You can't get women to be in studies for 10, 20 years. It's hard to do.

Q. Well, but a systematic review and a meta-analysis isn't going to tell you what the complications are going to look like at 8 or 10 or 15 or 20 years, correct?

A. Well, they will. When we get cohorts and RCT data out far enough, it will help us with that.

Q. So, then what I guess I'm trying to understand is you just told me that it's difficult

would consider that to be a serious complication or not, you just don't know that from looking at this?

A. No, I didn't say that I wouldn't -- if you classify -- it depends on like -- so, when I classify things as adverse events and serious adverse events, there is a standardized classification scale that we use when we are reporting clinical outcomes. These met the -- based on all sorts of criteria.

So, you didn't ask me if -- do I think it's an adverse event? They reported pain, yes. I just want it to be taken, that statement to be taken in context of -- I do think that they're different and I -- I think it's important to not talk about pain, immediate postoperative pain, the same way we are talking about prolonged pain.

Q. Would you agree with me that women who receive the obturator sling can have chronic groin pain that lasts longer than the immediate postoperative period?

A. Yes, I would.

Q. Would you agree with me that women who have the obturator sling can have chronic leg pain that lasts longer than the immediate postoperative

period?

A. I would.

Q. Would you agree with me that the obturator sling increases or -- use of the obturator midurethral sling increases the incidence of groin pain in women over women who have had the TVT Retropubic sling?

A. I would.

Q. Would you agree with me that the rate of women who have chronic leg pain following the obturator procedure is greater than that of women who have the retropubic procedure?

A. I would.

Q. And, so, you will agree with me that the TVT-O puts women at an increased risk for chronic groin pain over some of the other procedures, including the retropubic procedure, that's available, correct?

A. I would.

MR. ROSENBLATT: Object to form.

BY MS. FITZPATRICK:

Q. And you will agree with me that the TVT-O procedure puts women at an increased risk for chronic leg pain over the retropubic procedure,

correct?

MR. ROSENBLATT: Object to form.

BY THE WITNESS:

A. I would.

BY MS. FITZPATRICK:

Q. And you'll agree with me that 16% complaint of leg pain, whether it's immediately postoperative or chronic, is not rare?

A. Agree.

Q. And you'll agree with me that a 6.5% rate of groin pain, whether it's immediately postoperative or it's chronic, is not rare?

A. Yeah, I would say that a 6.5% rate of having a surgical site pain is not terrible.

You could argue that 100 percent of people should have pain.

I'm talking like short term. You have an abdominal incision, you have pain. But I agree that it should resolve quickly.

Q. I want you to take a look at 71.e10.

A. Okay.

Q. And, again, we are on Table 3 and I'm looking at vaginal perforations here.

And there was -- 20 studies were looked

at for the obturator sling, correct?

A. Correct.

Q. And there were a total of 82 events out of 2498 patients, 2,498 patients, correct?

A. Yes.

Q. And depending on the study, there was some studies, they ranged -- the rate of vaginal perforation associated with the obturator procedure ranged from zero up to 10.87%, correct?

A. That's correct.

Q. And would you agree with me that 10.87% rate of vaginal perforation is not rare in that -- according to that study?

A. Yes.

Q. The overall incidence of vaginal perforation was 2.8% for the obturator sling, correct?

A. Correct.

Q. And you'll agree with me that that's significantly higher than the 0.73% that is reported for the retropubic sling, correct?

A. Yeah. I mean, I think that if we are going to get into the details, I think one of the limitations with discussing vaginal perforations,

know which complications. Yeah.

Q. If the complication --

A. That's what I said.

Q. -- was included in Dr. Culligan's paper, it would be included somewhere in Table 3 associated with a pubovaginal sling?

A. I -- I think so, yes.

Q. Okay. Are autologous fascial slings an appropriate alternative to the transobturator -- TVT-O transobturator sling?

A. Yes.

Q. Is the Burch procedure an acceptable appropriate alternative to the TVT-O transobturator sling?

A. Yes.

Q. And neither of those procedures produces the same rate of groin pain or leg pain as does the TVT-O procedure, correct?

A. Correct.

MR. ROSENBLATT: Object to form.

BY THE WITNESS:

A. They have a different type of risk/benefit ratio.

BY MS. FITZPATRICK:

offer women both the TVT and the TVT-O procedure, correct?

A. That's correct.

Q. And you let them make the decision on which sling they want on based on the information that you give?

A. Of course.

Q. Do you counsel your patients that the TVT-O results in higher levels of leg and groin pain?

A. I do.

Q. Do you counsel them that it results in a higher rate of sling erosion and the need to return to the operating room?

MR. ROSENBLATT: Object to form.

BY THE WITNESS:

A. I think that those differences, when I look at my own outcome data through TOMUS, are negligible. So, I don't think that there is a significantly higher rate of vaginal erosion with a transobturator sling.

BY MS. FITZPATRICK:

Q. Okay.

A. I mean, I usually tell them this is what

doing my own procedure and not tell anybody.

And if I put any sort of a surgical instrument, whether it be a trocar that I made, whether it be a uterine packing forceps is what I personally used when I did fascial slings, like, and you put it through that space, you're going to have a higher rate of complications.

Like it's not that -- it's putting the thing through the space. It's not inherently a design flaw in the instrumentation.

Q. Could it have anything to do at all with being a blind procedure?

A. I mean, you can -- I think that your rate of -- I would -- I would hypothesize that your rate of having a bladder perforation, although in a blind procedure, would be -- or an injury to the thigh would be higher in a blind procedure than in an open, although we know even in open sling procedures when we actually did a Baker dissection, you could get them. So, it doesn't take it down to zero.

I think we are actually saying mostly the same thing. I just -- this is more for principle and it's got nothing to do with this.

Q. A Burch?

A. Yeah. Wrong trial.

Q. Okay. So, let me --

A. That's what you mean by native tissue repair. I mean, native tissue repair is usually prolapse operation.

Q. Yeah. You're right.

A. That's okay.

Q. And I'm trying to shortcut and I shouldn't be.

A. That's okay. I agree with that.

Q. So, let me put it this way.

A. I agree with that.

Q. So, you agree with me that a woman undergoing surgical intervention for an SUI, that a Burch procedure is an appropriate surgical intervention?

A. I think it should be discussed.

Q. Okay. And that an autologous fascial sling is an appropriate surgical intervention?

A. Yes.

Q. And the TVT-O is an appropriate surgical intervention?

A. Yes.

A. Are these recent IFUs? Just out of curiosity. I don't read them, as I indicated before.

Q. 2009.

MR. ROSENBLATT: I will just point out that the TVT-O IFU says 2005 on it.

MS. HOLCOMB: I think it's according to the chart you all provided. It was in use up until --

MS. FITZPATRICK: No, actually, the TVT-O is status 2010. So, it was in use, if you look on the front page.

MR. ROSENBLATT: Okay.

BY THE WITNESS:

A. I just want to make sure because a lot of the data that we've discussed has come out in like 2014 to '16.

BY MS. FITZPATRICK:

Q. Okay.

A. And I don't -- like I said, I don't use the IFUs, so I'm not familiar with them.

Q. Okay. Understanding that, I'm just --

A. But I will answer your questions.

Q. -- just wondering if you can tell me, looking at these two, if there is anywhere that

Ethicon advised physicians that there was a difference in the relative risks associated with the devices.

A. It seems like these are just general, like if you're doing surgery, you may injure an organ type.

Q. So, would you agree with me, at least from the IFUs that you looked at, there is no distinction drawn between the relative risks from the TVT -- I will call it the retropubic procedure versus the obturator procedure?

A. In an effort of time that you guys have, I'm going to assume that they're pretty much the same.

Q. Okay. I want you to take a look at it just quickly if you can. I'm not trying to --

A. Here it talks about transient leg pain in one.

That looks like there might be some differences.

Q. Okay. What do you see as the differences in them?

A. Like in the obturator one, it says, "Transient leg pain lasting 24 to 48 hours."

more --

Q. Yeah, I think if you are looking at the adverse events.

A. Okay. I am looking at the wrong page. I'm in "Warnings and Precautions."

Q. Or "Adverse Reactions."

A. Are you in "Warnings and Precautions"?

Q. No, I'm on "Adverse Reactions."

A. Much smaller list.

Q. I will admit some of this is extraordinarily hard to read.

A. Much smaller list. "Adverse Reactions."

Q. The adverse reactions are the same for the TVT and the TVT-O, correct?

A. Yes.

Q. So, there is nothing that in those -- that "Adverse Reactions" section that can alert the doctor to what you know and have testified about the difference in the risk profiles for these particular products?

A. Not in the "Adverse Reactions" portion. They're the same. But there is other information that can alert them.

Q. In the IFU? Tell me what's different.

A. "Transient leg pain lasting 24 to 48 hours." I'm pretty sure that isn't in the retropubic one. I mean, some are common sense.

Q. There is nothing in the obturator one about chronic leg pain, correct?

A. Not that -- is this -- yeah, there is.

Q. One slightly easier.

A. Not chronic, no.

Q. Chronic, yes. That's what I was asking.

There is nothing about --

A. Very short time.

Q. -- groin pain, but it's the transient one. Okay.

Anything else?

A. That's the only thing that like popped. Like in this other one they are talking about postoperative restrictions.

Q. I think that's in both of them.

A. Oh, yeah. It's higher up on the other one.

So, it seems that that's the primary difference.

Q. So, apart from the reference to the transient leg pain -- hang on. The brains of the